K072682

Pg 1 of 5

510(k) SUMMARY

Biolitec Inc.'s
50W Ceralas Diode 1950nm Laser System (Model D1950)

APR 18 2008

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hogan & Hartson
555 13th Street NW
Washington DC 20004

Phone: 202 637-5794
Facsimile: (202) 637-5910

Contact Person: Jonathan S. Kahan

Date Prepared: September 20, 2007

Name of Device and Name/Address of Sponsor

50W Ceralas D 1950nm Diode Laser (Model D1950)

Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Common or Usual Name

Diode Laser

Classification Name

Laser, Surgical Diode Laser System

Product Code and Regulation Number

GEX, 21 C.F.R. 878.4810

Predicate Devices

AllMed Revolix 120 Laser Systems (K033423, K051167, K070476)

Intended Use / Indications for Use

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral strictures
- Bladder neck incisions
- Ablation and resection of bladder tumors, urethral tumors and ureteral tumors
- Ablation of Benign Prostatic hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of the external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis

- Mallory-Weiss tear
- Gastric erosions

Thoracic/Pulmonary Surgery
Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Laryngeal lesions
- Airway obstruction including carcinoma
- Polyps and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

Ear, Nose and Throat (Otolaryngology)
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal/sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

K072682 PS 4 of 5

Dermatology/Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue in therapeutic plastic, dermatologic and aesthetic procedures including:

- Basal Cell carcinomas
- Lesions of the skin and subcutaneous tissue
- Skin tags
- Plantar warts

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

- Ablation of soft and cartilaginous tissue in minimally invasive spinal surgery including:
  - Percutaneous laser disc decompression/discectomy
  - Foraminoplasty
  - Ablation and coagulation of soft vascular and non vascular tissue

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystecomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma

- Debridement of decubitus ulcers
- Hemorrhoids
- Debridement of statis ulcers
- Biopsy

Technological Characteristics

The Ceralas D1950 is a diode laser operating at 1950nm with a maximum power output of 50W.

Performance Data

Bench testing was performed to compare the vaporization, cutting, and coagulation rates of the Ceralas D1950 and a 2010nm laser. The lasers were directed at potato slices and porcine muscle tissue to evaluate vaporization, and cutting and coagulation were evaluated with porcine liver, skin, and muscle tissue. Similar parameters were employed with each laser to test the effects of the Ceralas D1950 and the 2010nm lasers on the target tissue for each of these tests. The testing demonstrated substantially equivalent performance and tissue effects between the Ceralas D1950 and the 2010nm laser device.

Substantial Equivalence

The Ceralas D1950 is as safe and effective as AllMed Revolix Laser Systems (K033423, K051167, K070476). The Ceralas D1950 has the same intended uses and indications, and similar technological characteristics, and principles of operation as its predicate devices. Thus, the Ceralas D1950 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2008

Biolitec, Inc.
% Hogan & Hartson, LLP
Mr. Johnathan S. Kahan
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K072682
Trade/Device Name: 50W Ceralas D 1950nm Diode Laser (Model D1950)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 10, 2008
Received: March 10, 2008

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072682

Device Name: 50W Ceralas D 1950nm Diode Laser (Model D1950)

Indications for Use:

Urology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral strictures
- Bladder neck incisions
- Ablation and resection of bladder tumors, urethral tumors and ureteral tumors
- Ablation of Benign Prostatic hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of the external genitalia

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias

Nilay Patel for mkm
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072682

- Telangiectasias of the Osler-Weber-Renu disease
- Vascular malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric erosions

Thoracic/Pulmonary Surgery
Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Laryngeal lesions
- Airway obstruction including carcinoma
- Polyps and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

Ear, Nose and Throat (Otolaryngology)
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal/sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072682

Dermatology/Plastic Surgery
Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue in therapeutic plastic, dermatologic and aesthetic procedures including:

- Basal Cell carcinomas
- Lesions of the skin and subcutaneous tissue
- Skin tags
- Plantar warts

Arthroscopy
Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

- Ablation of soft and cartilaginous tissue in minimally invasive spinal surgery including:
  - Percutaneous laser disc decompression/discectomy
  - Foraminoplasty
  - Ablation and coagulation of soft vascular and non vascular tissue

General Surgery
Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystecomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma

Neil R. O'Hara for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072682

- Debridement of decubitus ulcers
- Hemorrhoids
- Debridement of statis ulcers
- Biopsy

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072682